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OPIOID USE IN THE CESAREAN SECTION PATIENT WITH THE
PREOPERATIVE ADMINISTRATION OF INTRAVENOUS ACETAMINOPHEN

by

Dana Edwards Bernardo

A Capstone Project
Submitted to the Graduate School
and the Department of Advanced Practice
at The University of Southern Mississippi
in Partial Fulfillment of the Requirements
for the Degree of Doctor of Nursing Practice

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ABSTRACT

OPIOID USE IN THE CESAREAN SECTION PATIENT WITH THE PREOPERATIVE ADMINISTRATION OF INTRAVENOUS ACETAMINOPHEN

by Dana Edwards Bernardo

December 2016

Cesarean sections are one of the most common surgical procedures and there are no current guidelines for the management of postoperative pain control (Darvish, Ardestani, Shali, & Tajik, 2013). Unresolved pain in this population can lead to long lasting problems, such as chronic pain and depression (Booth, Harris, Eisenach, & Pan, 2015). The goal of multimodal therapy with IV acetaminophen for CS mothers was to ensure a rapid and safe recovery process with reduced adverse complications and shortened hospital length of stay. The independent t-test was used to compare the mean time for length of stay, first request of pain medication, and total morphine equivalents needed 24-hours and 48-hours post-cesarean section between the treatment group, Group A and control group, Group C.

The results reflected that the preoperative administration of IV acetaminophen reveal that Group A had a shorter length of stay than Group C. The difference was statistically significantly different ($p = 0.022$). The amount of time for first request of pain medication was compared. Group A had a shorter length of time for first request of pain medication compared to Group C. The difference was not statistically significantly different ($p = 0.299$) indicating Group C had a longer time for opioid/analgesic intervention compared to Group A. Morphine milligram equivalents (MME) were compared between the two groups between 24 and 48 hours. The mean MME for Group

A and Group C was not statistically significantly different ($p = 0.299$) indicating there was no difference in MME between the two groups. The MME of 48 hours was higher in Group A than Group C and this difference was statistically significantly different ($p = 0.002$) indicating that those who did not receive preoperative administration of IV acetaminophen had a lower MME consumption.

Keywords: Ofirmev, paracetamol, intravenous acetaminophen, cesarean sections, postoperative pain control, multimodal analgesia

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DEDICATION

I would like to thank my Lord and Savior for giving me the ability and the opportunity to accomplish my goals. Also, to the loving memory of my dad, Jim: Thank you for inspiring me. You were constantly instilling the grit and the drive for me to 'be more' in life and for that, I am eternally grateful. I offer my most sincere gratitude to my mom, Carol. I could not have made this journey without you. Your constant encouragement and unwavering faith in me, especially when I had none in myself, is truly appreciated. To my beautiful daughter, Lillie: Thank you for your patience, your love, and your humor. You have helped me keep my sanity over the past three years and that means more than you know. I would also like to thank my family and friends for their love and support.

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LIST OF ABBREVIATIONS

<i>AACN</i>	American Association of Colleges of Nursing
<i>ASA</i>	American Society of Anesthesiologists
<i>CDC</i>	Centers for Disease Control and Prevention
<i>CI</i>	Confidence Interval
<i>C_{max}</i>	Maximum Plasma Concentration of Drug
<i>CRNA</i>	Certified Registered Nurse Anesthetist
<i>CS</i>	Cesarean Section
<i>CSF</i>	Cerebral Spinal Fluid
<i>DBP</i>	Diastolic Blood Pressure
<i>df</i>	Degrees of Freedom
<i>DNP</i>	Doctorate of Nursing Practices
<i>eMAR</i>	Electronic Medical Administration Record
<i>f</i>	Frequency
<i>FDA</i>	Food and Drug Administration
<i>gm/g</i>	Gram
<i>h</i>	Hour
<i>HR</i>	Heart Rate
<i>ICU</i>	Intensive Care Unit
<i>IV</i>	Intravenous
<i>LOS</i>	Length of Stay
<i>LOD</i>	Lines of Defense
<i>MAP</i>	Mean Arterial Pressure

<i>mcg</i>	Microgram
<i>mL</i>	Milliliter
<i>mg</i>	Milligram
<i>MME</i>	Morphine Milligram Equivalents
<i>Mean Diff</i>	Mean Difference
<i>n</i>	Number
<i>NICU</i>	Neonatal Intensive Care Unit
<i>NOPA</i>	Nonopioid Analgesic
<i>NSAID</i>	Nonsteroidal Anti-Inflammatory Drug
<i>OB/GYN</i>	Obstetrics/Gynecology
<i>PO</i>	By Mouth
<i>PR</i>	Per Rectum
<i>RCT</i>	Randomized Controlled Trials
<i>SBP</i>	Systolic Blood Pressure
<i>SE Diff</i>	Standard Error Difference
<i>SEM</i>	Standard Error of the Mean
<i>Std Dev</i>	Standard Deviation
sig. (2-tailed)	Test Statistic and Degrees of Freedom Matching <i>p</i> Value
<i>SE</i>	Side Effects
<i>SNS</i>	Sympathetic Nervous System
<i>t</i>	Computed Test Statistic
<i>Tmax</i>	Maximum Plasma Concentration Time
<i>THA</i>	Total Hip Arthroplasty

<i>vs.</i>	Versus
<i>VAS</i>	Visual Analogue Scale
<i>VPS</i>	Visual Pain Scale
<i>WMD</i>	Weighted Mean Difference

CHAPTER I – INTRODUCTION

Surgical pain experienced by any patient can be challenging for caregivers to regulate effectively. Managing postoperative pain for the cesarean section (CS) patient is different from other surgical procedures (Cancado, Omais, Ashmawi, & Torres, 2012). Treatment of acute pain for the CS mother should be fast and safe in order to effectively take care of the newborn (Cancado et al., 2012). If acute pain is not managed properly for CS mothers, unresolved pain can lead to chronic pain for 10-15% of mothers (Orbach-Zinger et al., 2014). The development of postpartum depression and post-traumatic stress disorder can also occur while enduring acute pain during childbirth (Orbach-Zinger et al., 2014). In addition to decreased comfort, acute pain can cause many adverse complications by stimulating the sympathetic nervous system (SNS), leading to tachycardia, hypertension, and arrhythmias (Nagelhout & Plaus, 2014). Unrelieved pain has been linked to metabolic disturbances by interfering with the endocrine system, impairing cognitive function, depressing the immune system, and inducing high anxiety states, which in turn affects digestion, heart rate, breathing and other key bodily functions (Nagelhout & Plaus, 2014).

Background

Cesarean sections are increasing every year and there is concern for maternal health relating to this type of delivery (Cancado et al., 2012). The common complaint for these patients is postoperative pain (Orbach-Zinger et al., 2014). These patients present with distinct challenges with the use of opioids. In addition to the aforementioned problems to which pain can contribute to, other impairments found in the cesarean patient related to the use of opioids are decreased alertness and stamina needed

to take care of and breastfeed their newborn child (Ismail, Shahzad, & Shafiq, 2012). Instead of utilizing opioids only, a multimodal approach should be implemented when treating postoperative pain for cesarean deliveries (Valentine, Carvalho, Lazo, & Riley, 2015).

The American Society of Anesthesiologists Task Force on Acute Pain urges multimodal pain control methods unless contraindicated (Nishimoto, 2014). Multimodal analgesia involves the combination of opioids along with nonopioid analgesics or NOPAs (Pogatzki-Zahn, Chandrasena, & Schug, 2014). Most commonly, NOPAs are recommended as the choice agent and opioids are to be used as supplemental agents. The NOPAs' efficacy and safety should not be a concern and should provide favorable results for pain control (Pogatzki-Zahn et al., 2014). Incorporating a multimodal approach to reducing acute pain and promoting comfort may help avert the long-term effects of chronic pain and depression that occur in CS patients (Booth, Harris, Eisenach, & Pan, 2015).

Significance

Postoperative pain negatively affects the patient's quality of life. Adverse effects of improper pain management by the anesthesia provider before and during surgery can lead to physical and emotional complications postoperatively (Pasero & Stannard, 2012). Ambulation can be delayed which can lead to venous thromboembolism, rehabilitation can be shortened or missed, depression and anxiety may develop, and hospital readmissions can occur (Pasero & Stannard, 2012). These compounded problems can lead to decreased patient satisfaction (Cancado et al., 2012). Therefore, pain management should be a primary concern for the anesthesia provider. The goal of the

anesthesia provider is to provide the safest and the best pain control methods to enable the safest and easiest recovery possible.

Clinical Question

Does the use of preoperative administration of IV acetaminophen decrease the use of opioids compared to those who do not receive IV acetaminophen by women who have given birth by CS? Cesarean section is one of the most common procedures in the field of obstetric/gynecologic (OB/GYN), yet there are no guidelines for treating post-cesarean pain (Darvish et al., 2013).

Hamilton and colleagues (2015) reveal that of the 51.4 million surgical procedures that take place annually in the United States alone, approximately 1.3 million of these surgical procedures are CS. Frequency of cesarean sections surgeries is second only to arteriography and angiocardiology (Hamilton et al., 2015). Because long lasting effects can arise from insufficient analgesia, an alternative approach for post CS pain is indicated. An estimated 30%-40% of CS patients experience moderate to severe pain postoperatively, which can lead to fear, anxiety, and depression (Ayatollahi, Faghihi, Behdad, Heiranizadeh, & Baghianimoghadam, 2014). When CS pain is managed appropriately ensuring a safe and rapid recovery, a CS mother could have more favorable results from breastfeeding and bonding experiences with her child (Niklasson, Arnelo, Ohman, Segerdahl, & Blanck, 2015).

Problem Statement

In the United States, cesarean section (CS) accounts for more than 25% of all deliveries (Kessous, et al. 2012). There is a marked increase in CS that can be attributed to legal issues within the obstetrics/gynecological (OB/GYN) departments, as well as an

increase in the number of mothers, that due to their age or their socioeconomic class, are considered high-risk (Darvish et al., 2013). With the dramatic increase in cesarean deliveries performed each year, the management of postoperative pain and other complications is becoming more relevant than ever before (Darvish et al., 2013).

Insufficient analgesia can create long-term problems; in contrast, the safe, uncomplicated, and rapid recovery CS mothers receive via multimodal treatment can help reduce adverse complications, shorten the hospital stay, and improve breastfeeding, which leads to quality bonding between a mother and her child (Niklasson et al., 2015). Also, effective management of the acute surgical pain experience in CS patients can help prevent future problems with chronic pain and depression (Booth et al., 2015).

Purpose of the Project

The purpose of this doctoral project is to foster a change in clinical practice for the management of postoperative pain for CS patients. The use of a multimodal approach with nonopioids, such as IV acetaminophen and opioids as a supplement for breakthrough pain, is becoming increasingly commonplace in many surgical procedures (Lachiewicz, 2013). This study explored the impact of preoperative administration of IV acetaminophen and determined if the administration reduced the mean time for length of stay, first request of pain medication, and the total morphine equivalents needed 24-hours and 48-hours post-cesarean delivery when compared to those who did not receive IV acetaminophen prior to CS.

Length of stay was calculated in hours beginning with anesthesia start time and ended when the patient was discharged from the hospital. The time of first request of pain medication was calculated in minutes and hours starting with the anesthesia time

until the patient first asked for pain medication. Total morphine milligram equivalents were calculated by totaling the analgesics given in a 24-hour and 48-hour time period.

Acetaminophen History and Trade Names

For over a century acetaminophen has been used as a safe and effective medication for analgesia, as well as an antipyretic in both oral and rectal suppository forms (Pasero & Stannard, 2012). It was first synthesized in 1878, with clinical use starting worldwide the following year; however, it was not until the 1950s that acetaminophen was sold in the United States (Pasero & Stannard, 2012). Since then, it has become one of the most conventional and best known medications for the treatment of fever and mild to moderate pain for children and adults (Pasero & Stannard, 2012).

Ofirmev®, also known as paracetamol in Europe, is the intravenous version of acetaminophen. In 2001, paracetamol was manufactured by Cadence Pharmaceuticals and was available for use in over 80 countries, excluding the United States (Buck, 2011). The Food and Drug Administration (FDA) granted permission on November 2, 2010, for the use IV of Ofirmev®, in the United States (Buck, 2011). The FDA supports the use of IV acetaminophen for: “1) the management of mild to moderate pain; 2) the management of moderate to severe pain with adjunctive opioid analgesics; and 3) the reduction of fever in adults and children (age ≥ 2 years)” (Pasero & Stannard, 2012, p. 108).

Because IV acetaminophen avoids the first-pass metabolism, the drug spares the liver from 50% of exposure compared to the oral or rectal form of acetaminophen (Lewis, 2012). The elimination of the first-pass metabolism and the rapid onset of IV acetaminophen is quicker and more predictable than other available routes (Pasero & Stannard, 2012).

Cost of Acetaminophen

Despite the reported benefits and the elimination of the hepatic first pass metabolism, the cost of the product decreases its availability (McKee, 2014). When the price of IV acetaminophen increased 140%, from approximately \$14.00 per 1 gm vial to \$35.00 per 1 gm vial (Dungy & Prince, 2015) many hospitals responded to the substantial rise in costs by decreasing their use of the product, thereby decreasing the availability of the drug.

Acetaminophen Mechanism

IV acetaminophen is an analgesic and an antipyretic with a site of action that is speculated to occur at the central nervous system (Lachiewicz, 2013). Its analgesic properties are theorized to act by inhibiting prostaglandins, which then act peripherally by blocking pain impulses, specifically a cannabinoid receptor agonist mechanism, a serotonergic (5-HT) mechanism, cyclooxygenase-3 isoenzyme inhibition, and TRPV-agonist (Lachiewicz, 2013). The antipyretic effect also is caused also by prostaglandin inhibition within the hypothalamus and the subsequent blocking of the cannabinoid agonist mechanism (Pasero & Stannard, 2012).

Route Comparisons Supporting IV Administration

In comparisons of by mouth (PO), per rectum (PR), and IV forms of acetaminophen, the IV form has significantly higher peak concentrations in cerebrospinal fluid (CSF) because high plasma concentrations are readily able to cross the blood brain barrier (Lachiewicz, 2013). This is important, since acetaminophen is believed to work centrally. Passive diffusion of acetaminophen into the central nervous system via the blood brain barrier is dependent on Cmax (maximum plasma concentration of drug) since

active transport does not occur (Singla et al., 2012). Also, there is less variability in the plasma concentrations in cases where IV acetaminophen is delivered instead of the PO or PR form (Singla et al., 2012).

The advantages of the IV form of acetaminophen over the PO route lie primarily in its concentration and its onset time. For acetaminophen to be an effective analgesic, serum therapeutic level should be 16 mcg/mL in adults (Golembieewski & Mueller, 2011). It takes 45 minutes for the onset of action to occur for 1,000 mg of PO acetaminophen and most patients are unable to reach median plasma concentrations of 12mcg/mL (Golembieewski & Mueller, 2011). The PR form of acetaminophen is unpredictable, and the maximum plasma concentration (Tmax) time can take up to three to four hours (Lachiewicz, 2013). In contrast, IV acetaminophen can reach Tmax of 19 mcg/mL within 15-30 minutes (Lachiewicz, 2013).

Acetaminophen is generally safe for adults when taken in doses no greater than 4g/day, and in doses of 2-3 g/day for chronic use (Groudine & Fossum 2011). Acetaminophen toxicity can occur in doses greater than the recommended amount. Also, acetaminophen is an ingredient in cold and sinus medicines and other over-the-counter medications. This can be a safety concern when these medications are used in combination with prescribed medications. However, these concerns can be addressed and alleviated in the hospital setting with diligent pharmacy, physician, and nursing supervision.

Acetaminophen should be used with caution or avoided in patients with acute liver disease or hypersensitivity to acetaminophen, as hepatotoxicity is a major safety concern (Golembieewski & Mueller, 2011). Underlying causes of hepatotoxicity can

include alcohol abuse, liver steatosis, depletion of glutathione stores, and chronic malnutrition. Acetaminophen is metabolized by the liver through 3 enzymatic pathways: glucuronidation, sulfation, and oxidation (Lachiewicz, 2013). The renal system is responsible for excreting 3-5 percent of metabolized acetaminophen; therefore, this is a medicine that should be avoided in patients with severe hypovolemia or severe renal impairment.

Hepatotoxicity from the absorption of PO acetaminophen can result in high concentrations in the portohepatic circulation resulting from the first pass effect (Lachiewicz, 2013). IV acetaminophen avoids the hepatic first pass effect but is able to accomplish higher plasma concentrations. However, there is no supporting evidence to show that giving IV acetaminophen will result in less hepatotoxicity than occurs with the PO or PR forms.

Intravenous Acetaminophen Administration

While the mechanism of action is unclear, there are many benefits from IV acetaminophen. Unlike opioids, IV acetaminophen neither increases the incidence of nausea and vomiting or respiratory depression. The drug does not cause platelet dysfunction that can contribute to gastritis or interfere with renal function, like many nonsteroidal anti-inflammatory inhibitors (NSAIDs) are known to do (Pasero & Stannard, 2012).

After the administration of IV acetaminophen, the onset time for action occurs between 5 to 10 minutes, and peaks after 1 hour for analgesia purposes (Nagelhout & Plaus, 2014). The medication lasts between four to six hours after its infusion. Also, IV acetaminophen has been shown to have higher peak plasma and cerebrospinal fluid (CSF)

maximum concentrations than oral or rectal suppository forms (Singla et al., 2012).

These concentrations also peak earlier compared to the oral (PO) and suppository form (PR) of acetaminophen. It should also be noted that IV acetaminophen's C_{max} is nearly twice that of the PO form of acetaminophen and almost four times greater than that of the PR form of acetaminophen (Singla et al., 2012). This means that the IV form of acetaminophen results in a faster onset, making it more advantageous compared to the other routes of administration.

Summary

CS are increasing every year and pain management in this population is concerning. If surgical pain for the CS patient is not treated effectively, serious complications such as depression and chronic pain can occur. Traditionally opioids have been used to treat postoperative pain but are known to have serious, negative side effects. It is recommended by the American Society of Anesthesiologists Task Force on Acute Pain Management to use a multimodal approach to treat pain.

Multimodal therapy is designed to use nonopioid analgesics to treat pain and opioids are given as supplemental breakthrough agents. IV acetaminophen is proven to be a safe and effective drug when used properly and is a favorable choice for multimodal therapy.

Although the cost of IV acetaminophen has increased, it is more beneficial when compared to other forms of acetaminophen.

CHAPTER II – REVIEW OF LITERATURE

A systematic search for current articles was conducted using Cochrane, Pub Med, Nursing Ovid, Medline, CINAHL, Joanna Briggs Institute, and Google Scholar, Agency for Healthcare Research and Quality, and National Guidelines Clearinghouse. Search terms were: *ofirmev and postoperative pain management, intravenous (IV) Tylenol and postoperative pain control, paracetamol and cesarean section, guidelines for postoperative pain control for CS patients, and IV acetaminophen and c-sections and reduction of pain*. This search returned 525 publications.

Included articles were five years current, written in English, manufacture-produced publications, and related to a multimodal analgesic regimen. Articles were excluded if: they were written in a language other than English, ongoing studies, partial studies, used animals as test subjects, demonstrated conflicts of interest, or irrelevant to CS patients receiving IV acetaminophen as a multimodal analgesic regimen. Since there was limited data for IV acetaminophen used as a multimodal approach to pain management for CS patients, this project synthesizes the published literature about: (a) IV acetaminophen for pain management, (b) different surgeries that implement IV acetaminophen for multimodal pain reduction, and (c) benefits with IV acetaminophen for CS. Thirteen peer-reviewed articles were relevant to IV acetaminophen used in a multimodal approach to pain management. Three of those articles are relevant to CS patients.

Intravenous Acetaminophen for Pain Management

In a qualitative report, Groudine and Fossum (2011) examined the results of eight different studies with multiple surgical procedures. Studies included manufacture

produced publications, randomized, double-blind, placebo-controlled, multicenter, multiple-dose studies, and a meta-analysis of randomized, prospective trials. These results showed the safety and efficacy of IV acetaminophen for various procedures, including pediatric and pregnant patients. These authors observed that the implementation of IV acetaminophen had a positive impact on patient care when used in a multimodal therapy to treat acute surgical pain. Additionally, the study results revealed a reduction in pain when IV acetaminophen was used in major surgical procedures. Groudine and Fossum (2011) concluded that IV acetaminophen is relatively safe, but should be used with strict clinical supervision because it is contained in many over-the-counter medications and oral narcotics. If medications are not monitored closely, there is an increased risk of exceeding the recommended daily allowance of acetaminophen. The authors also acknowledged that hepatic damage is related to overdose of acetaminophen and contraindicated in patients with hepatic impairments (Groudine & Fossum, 2011). Even so, IV acetaminophen could be a reasonable component of NOPAs because it is not associated with increased bleeding after surgery and does not affect kidney function (Groudine & Fossum, 2011).

Pasero and Stannard (2012) performed a qualitative, case-illustrated review study showing the benefits of IV acetaminophen. The information revealed the results from various case studies, including laparoscopic surgeries, major abdominal procedures, major orthopedic surgeries, dental procedures, and pediatric procedures. This case review evaluated the safety and effectiveness of IV acetaminophen and concluded that the medication is beneficial for the use as an adjunct, along with other opioids, for multimodal pain control (Pasero & Stannard, 2012).

It was revealed for major abdominal surgeries, 40 patients were randomized to receive either 1000 mg of IV acetaminophen every six hours and IV meperidine for breakthrough pain or placebo, which was IV saline every six hours and IV meperidine as needed within a 24-hour time period. The treatment group needed less postoperative meperidine ($p < 0.05$) and their visual analog scale (VAS) scores were lower ($p < 0.01$) when compared to the control group (Pasero & Stannard).

IV acetaminophen has been shown to retain its safety features, even though it reaches a higher maximum concentration (70%) and faster onset than with PO and PR administrations. These findings help secure IV acetaminophen's standing as an attractive component for multimodal pain relief, based on its ability to reduce the need for narcotics after surgery, thus reducing the risk of adverse opioid-related events (Pasero & Stannard, 2012). Adding IV acetaminophen could potentially have a dramatic impact on patient recovery rates, as it could facilitate mobilization and rehabilitation, which could mean reductions in health care costs and improvements in reported patient satisfaction (Pasero & Stannard, 2012).

Macario and Royal (2011) performed a meta-analysis to assess the analgesic benefits of IV acetaminophen for postoperative pain management for adults. Randomized, controlled trials (RCTs) comparing IV acetaminophen vs. an alternative analgesic or a placebo were retrieved from Medline and Cochrane library for the meta-analysis. From the RCTs, 22 studies were compared: IV acetaminophen vs. an alternative analgesic, such as parecoxib, IV metamizol, and PO ibuprofen, ($n = 8$ studies) and IV acetaminophen vs. a placebo ($n = 14$) (Macario & Royal, 2011). The results showed similar outcomes between IV acetaminophen and an alternative analgesic.

However, when the IV acetaminophen was compared to the placebo, 12 of the 14 studies found that IV acetaminophen patients experienced less pain (Macario & Royal, 2011). Even more impressive, 10 of the 14 placebo studies showed that when patients received IV acetaminophen, they not only needed fewer opioids overall and percentages of opioids for rescue pain, but also waited longer time intervals before needing opioids for pain relief (Macario & Royal, 2011).

De Oliveira, Castro-Alves, and McCarthy (2015) conducted a meta-analysis that implemented the random-effect model. The purpose of the study was to determine the effects of pain outcomes when a single dose of systemic acetaminophen is delivered before surgery in both adults and children. In this analysis, 11 RCTs were used to evaluate 740 patients, 375 having received a single dose of IV acetaminophen and the remaining 365, controls, receiving a placebo. The Jadad Scale was used to grade the RCTs and the median, and the interquartile range was four. From the 11 RCTs, nine studies evaluated the effect of systemic acetaminophen and noted its ability to help reduce postoperative opioid consumption when compared to the control (De Oliveira et al., 2015). There was a reduction of opioids needed by patients when given IV acetaminophen compared to placebo, weighted mean difference (WMD) of -9.7; 95% CI (-13.0 to -6.4). Also, the study showed IV acetaminophen was useful in a reduction of early pain at rest (≤ 4 h, -1; (95% CI (-2.0 to -0.2)) and pain at movement immediately postoperatively (24 h, -1.9; (95%CI (-2.8 to -1.0)) when compared to the control. From this information, the researchers concluded that a single dose of IV acetaminophen is a valuable medication to help diminish postoperative pain (De Oliveira et al., 2015).

Konstantatos, Smith, and Angliss (2012) investigated whether the addition of IV acetaminophen administration helped reduce discharge times in ambulatory surgery centers. For this study, 145 patients were divided as follows: pre and postoperative placebo (n = 50), operative IV acetaminophen and postoperative PO acetaminophen (n = 49), and pre and postoperative PO acetaminophen (n = 48). The authors determined that time ready for discharge from the postoperative care unit did not vary among the three groups (Konstantatos et al., 2012).

The researchers noted several limitations that may have impacted this study's conclusions. The dominant population of this study was young males having minor orthopedic and plastic surgery at only one ambulatory surgery center (Konstantatos et al., 2012). Healthy young males with an ASA I or II are less likely to develop respiratory depression or other side effects of opioids that are seen in older patients, patients with comorbidities, and obese patients (Konstantatos et al., 2012). Another weakness of the study could have been related to surgeons infiltrating local anesthetics at the site of incision and anesthesia personnel using fentanyl or other opioids. The aim of the study was to avoid altering the typical flow and treatment options used at the surgery center (Konstantatos et al., 2012).

Surgeries Implementing Intravenous Acetaminophen for Multimodal Pain Reduction *Gynecological Procedures*

Wininger et al. (2010) conducted a double-blind, placebo-controlled, parallel-group study in 17 different facilities throughout the United States. A total of 244 abdominal laparoscopic surgery patients were placed into four groups randomly: (a) IV acetaminophen 1 gm in 100 mL every 6 hours, (b) IV acetaminophen 650 mg in 65 mL

every 4 hours, (c) 100 mL of IV placebo every 6 hours, and (d) 100 mL IV placebo every 4 hours. All medications were given over a 15-minute period for 24 hours after surgery. The results showed that both IV acetaminophen groups outperformed the two placebo groups in terms of pain relief, reducing the weighted sum of pain intensity over a 24-hour period (1000 mg, $p < 0.0007$; 650 mg, $p < 0.019$) (Wininger et al., 2010).

Another study revealed that IV acetaminophen was given preoperatively and the medication's analgesic effects were assessed in 76 women who elected to have abdominal hysterectomies (Moon, Lee, Lee, & Moon, 2011). This study was a randomized, double-blinded and placebo-controlled, and was designed to learn whether IV acetaminophen administered prior to surgery would decrease pain scores, lessen the need for opioids, and reduce side effects. These patients were divided into two groups: Group A, IV acetaminophen 2 gm, 30 minutes before surgery with general anesthesia and Group C, IV placebo 30 minutes prior to surgery with general anesthesia. The results showed less need for opioids in Group A compared to group C ($p = 0.013$) (Moon, Lee, Lee, & Moon, 2011). It was noted that postoperative nausea and vomiting was also lower in Group A ($p = 0.05$) when compared to group C. Even though the patients in Group A needed fewer opioids and experienced less SE after surgery, they did not report a reduction in pain intensity (Moon et al., 2011).

Spinal Procedures

An IV acetaminophen group used significantly less opioids ($p = 0.015$) compared to the control group in a retrospective analysis conducted by Smith and Hoefling in 2014. The analysis reviewed 68 EMRs, including 34 patients who were selected to be in the control group and 34 spinal surgery patients who underwent spinal fusions with anterior

or posterior approaches and received IV acetaminophen either preoperatively or postoperatively (Smith & Hoefling, 2014). Members of the control group were close in age and gender to members of the medication group; they had the same surgery performed by the same surgeon, and received only opioids for pain control (Smith & Hoefling, 2014). Results indicated that there was a decreased need for opioids (11.3 mg morphine equivalent [ME]) in the group that received IV acetaminophen compared to the control group (20.6 ME). Both groups were similar when it came to VAS scoring, and needing post-surgery anti-emetics and laxatives (Smith & Hoefling, 2014).

Orthopedic Procedures

Total hip arthroplasties (THA) represent one of the most common musculoskeletal surgeries and one of the most arduous to handle in terms of pain management, due to comorbidities and to the advanced age of patients undergoing the procedure (Singla et al., 2014). Two double-blind, parallel-group, multicenter, randomized, placebo-controlled clinical trials were conducted on 130 participants with similar demographics to determine efficacy and safety of a single-dose IV acetaminophen for patients who underwent THAs. IV acetaminophen when compared to placebo, shows a higher mean pain intensity difference (PID) with significant ($p < 0.5$) differences in treatment arms.

Study one results indicated that pain relief scores were superior with IV acetaminophen beginning at T0.25, and study two results put it superior beginning at T0.5. Both studies continued to show favorable relief scores until T4. Rescue opioid consumption was reduced for up to six hours in study one and almost four hours in study two with IV acetaminophen. Essentially, both studies show that IV acetaminophen is an

effective multimodal analgesic, which has a rapid onset, decreases rescue medication, decreases opioid consumption by 50 percent, and reduces moderate-to-severe pain after THAs compared to placebo.

Benefits of Intravenous Acetaminophen for Cesarean Section

Kamath and Lasrado (2014) compared the efficacy of 2 gm butorphanol (an opioid) versus 1 gm intravenous acetaminophen for elective cesarean sections and routine gynecological procedures in a randomized parallel-group controlled trial. The 51 patients in Group A were given 1 gm of IV acetaminophen every eight hours. The 50 women in Group B received butorphanol 2 gm every 12 hours (Kamath & Lasrado, 2014). Pain was measured by VAS scales at rest and while the patient inhaled deeply. These scores were measured after 30 minutes, 2 hours, 4 hours, 6 hours, 8 hours, and increased to 12 hours, and 24 hours. Tramadol 100 mg IV was the rescue medication given if the pain intensity was greater than five (Kamath & Lasrado, 2014).

Kamath and Lasrado's (2014) results indicated that the Group B had better pain ratings at 2 hours than Group A (3.613 vs. 4.20). The pain ratings in both groups continued to decrease overtime and overall, the authors concluded that Group A was an effective and safe analgesic and it provided better pain-control at 6 hours, 8 hours, and 24 hours than Group B ($p = 0.02$). The remaining time intervals show no statistically significant difference between the two groups (Kamath & Lasrado, 2014). The study results illustrated less rescue medication was needed in Group A (68%) than Group B (92%) which concluded that there was a statistically significant difference ($p = 0.003$) favoring IV acetaminophen to butorphanol (Kamath & Lasrado 2014).

The authors advised that IV acetaminophen is not a good choice for monotherapy for pain control, but noted that when used in combination with other opioids, it reduced the side effects commonly seen with opioids (Kamath & Lasrado, 2014). Side-effects reported included: sedation was not seen in Group A and Group B reported 47%; nausea for Group A was 4 % compared to 14% for Group B; and Group A revealed it had less sleep disturbances (8%) compared to Group B (25%) (Kamath & Lasrado, 2014).

A randomized, double-blind, double-dummy, parallel group placebo-controlled clinical trial, 111 women had elective CS with spinal anesthesia, followed by a patient-controlled epidural (Paech, McDonnell, Sinha, Baber, & Nathan, 2014). Group C, the control group consisted of 23 women, who received a placebo, and Group PC had 30 women and they received 40 mg of IV parecoxib along with PO celecoxib 400 mg every 12 hours along with placebos. Group PA had 32 subjects and they received 2 gm IV paracetamol (IV acetaminophen) along with 1 gm PO paracetamol at 6, 12, and 18 hours along with placebos (Paech et al., 2014). Group PCPA had 26 women to receive 40 mg IV parecoxib and 2gm IV paracetamol, followed by 1 gm PO paracetamol at 6,12, and 18 hours in combination with 400 mg PO celecoxib.

The results of this study concluded that all three groups continued to need pain control from the pethidine epidural (Paech et al., 2014). The dynamic pain scores, as measured by the verbal numerical rating score, were not different in the groups, but the need for PO tramadol was least needed in the PCPA group (incidence 23% versus 48%, 70% and 58% in groups C, PC, and PA respectively, $p = 0.004$). The incidence of nausea and sedation was stable in all groups, with very little degree in differences (range 9% to 19%) (Paech et al., 2014). Concomitant pruritus and its severity were much greater in all

groups when compared to the control group (69%, 69% and 62 % versus 30%, $p = 0.016$). These results concluded that delivering COX-2 inhibitors and paracetamol, alone or in combination, does not reduce patients' decision to self-administer pethidine epidural analgesia (Paech et al., 2014).

Darvish and colleagues (2013) illustrated that the combination of IV acetaminophen and diclofenac has a better efficacy for controlling postoperative pain and reduced the need for additional opioid consumption. The authors selected 120 women candidates. These candidates were randomly placed into two groups. Group A participants received a diclofenac suppository at the end of CS with an additional 1 gm infusion of IV acetaminophen. The second group, Group B, received 20 mg bolus of meperidine while transitioning to the recovery room (Darvish et al., 2013).

Postoperative pain was noted in the recovery room 23.3% and 38.3% in Group A and Group B, respectively ($p=0.009$). Six hours after the procedure, postoperative pain was assessed and noted to be 16.7% and 38.7% in Groups A and B, respectively ($p=0.010$). Twelve hours after the procedure, pain was present and assessed to be 15% and 38.3% for Groups A and B, respectively ($p=0.002$) (Darvish et al., 2013). Meperidine was used as a supplement for pain control for both Groups A and B 6 hours after the CS and the pain present was noted 6.7% and 26.7%, ($p=0.013$).

Meperidine was used as a supplemental medication for breakthrough pain 12 hours after surgery and pain present was none and 16.7%, for patients in Groups A and B, respectively ($p=0.004$) (Darvish et al., 2013). The authors noted that the adverse effects from the medications used in both groups were the same ($p > 0.05$). From the information gathered, it appeared that the multimodal combination of diclofenac and IV

acetaminophen was a better postoperative pain control method when compared to meperidine alone (Darvish et al., 2013).

Review of Literature Summary

Opioids are known to have many undesirable side effects. However, IV acetaminophen has proven to be a safe and efficient means of reducing opioid consumption. To date, no clear or established guidelines are in place for reducing postoperative pain for CS patients (Darvish et al., 2013). Since IV acetaminophen's introduction to the United States, however, many studies have shown its importance as a multimodal agent for reducing the need for opioids in various surgical procedures. This information is limited within the CS delivery population. Through the implementation of IV acetaminophen, a safer and more reliable approach to pain control can be implemented for CS patients. Since many opioids do contain acetaminophen, it is important to monitor the amount of acetaminophen consumed by the patient. Proper clinical supervision can prevent exceeding the maximum daily dose of acetaminophen.

Theoretical Framework

Implementing evidence-based practice guidelines, the anesthesia provider or nurse anesthetist (CRNA) will ensure the best available health care techniques resulting in favorable patient outcomes. Due to the complexity of healthcare, models or theories can offer a framework to achieve a maximum level of wellness for patients (Riehl & Roy, 1980). Theories influence the way anesthesia providers base and formulate methods to implement the best care and speed of recovery for their patients. The application of the appropriate theory may encourage better techniques of nurse anesthesia practice for promoting relief of pain for the CS patient.

Neuman systems model was introduced in the 1970s for nursing education and practice. This theory has undergone many refinements, but remains a holistic approach to guiding nursing practice. The Neuman model is an open system model that deals with stress and reactions in relation to a client or group (Neuman & Fawcett, 2002). The theory posits that clients or groups are in a constant state of fluctuation, either moving towards wellness or illness (Neuman & Fawcett, 2002). The goal is for a patient to achieve harmony and stability when faced with internal or external stressors (Neuman & Fawcett, 2002).

Each individual is considered unique and possess characteristics that are considered normal within a basic structure (Neuman & Fawcett, 2002). Neuman's model shows the interrelationship of five variables that can affect the patients' well-being: (a) physiological, (b) psychological, (c) sociocultural, (d) developmental, and (e) spiritual (Butts & Rich, 2015). These variables aid in adapting to stressors, whether stressors are good or bad. According to Neuman and Fawcett (2002), these variables are part of the client's basic structure, as well as the normal and flexible lines of defense (LOD) and the lines of resistance that aid in maintaining balance for the patient's core (Neuman & Fawcett, 2002).

Neuman's Systems Model Diagram Explained

Neuman explains her theory by using a diagram. The illustration shows a circular module and it is known as the basic unit or the patient's core. It is surrounded by lines of resistance and a normal and flexible LOD. The LOD are in place to ensure the stability of a patient when threatened by known or unknown stressors (Neuman & Fawcett, 2002).

The flexible LOD is the outermost boundary surrounding the core and acts as a buffer to protect the patient's stable state (Neuman & Fawcett, 2002). This line is dynamic and can adapt to an emergent situation or other medical conditions, such as dehydration or depression. If the flexible LOD is penetrated, the patient will exhibit symptoms related to the stressor (Neuman & Fawcett, 2002).

The normal LOD is protected by the flexible LOD (Neuman & Fawcett, 2002). The normal LOD is known to be dynamic, expanding or contracting over time. The normal LOD and the five client variables represent the patient's standard state of health (Neuman & Fawcett, 2002). However, deviation from this standard determines the extent of damage received by the stressor. Stability of the patient's core can increase, diminish, or stay the same based on the normal LOD ability to deal with internal or external stressors (Neuman & Fawcett, 2002).

The innermost boundary protecting the patient's core is the line of resistance (Neuman & Fawcett, 2002). If the normal LOD are ineffective to an environmental stressor, the lines of resistance aid in protecting the core's integrity (Neuman & Fawcett, 2002). Effective lines of resistance assist in reversing damage from stressors and reestablishing order of the system. However, if the lines of resistance prove ineffective, permanent damage or death may result (Neuman & Fawcett, 2002).

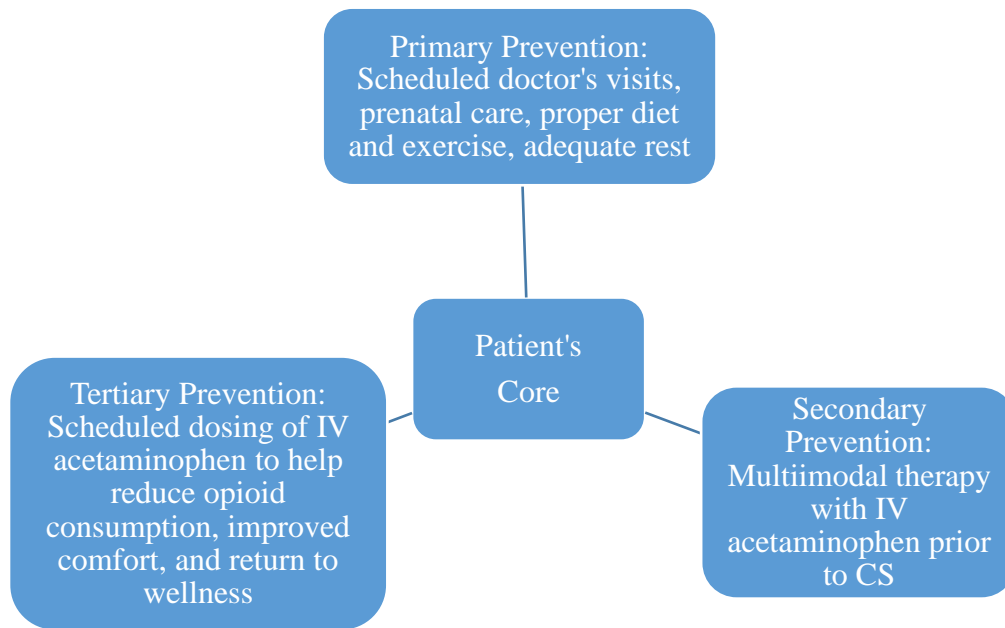


Figure 1. Adaptive Framework of Neuman's Model for CS Patients

Prevention Measures

Neuman's model is composed of primary, secondary, and tertiary preventions used to deal with environmental stressors (Neuman & Fawcett, 2014). All three prevention modalities act as interventions depending on the patient's condition. Based on the patient's stressors and conditions, these interventions can occur either alone or simultaneously (Zaccagnini & White, 2014).

Primary prevention is known as an intervention and wellness retention (Neuman & Fawcett, 2002). Primary intervention is used when there is a known threat to the patient's basic structure but has not occurred. This primary prevention helps enable or strengthens a system's ability to cope with stressors, possibly even before the stressor can affect the system (Butts & Rich 2015).

If the primary prevention is ineffective, the secondary prevention is needed to protect the patient's core by strengthening the internal lines of resistance (Neuman &

Fawcett, 2002). This can be achieved by treating symptoms to provide optimal wellness and stability. If the secondary prevention is ineffective, the patient's core is irreparably damaged. But, if the secondary prevention is adequate, reestablishment is made and the system can return to its previous level of function or stabilize to a lower or even higher level of functioning (Neuman & Fawcett, 2002).

The tertiary prevention is utilized when the secondary prevention is proven to be effective. Once the patient begins to return to their normal state of wellness, the tertiary prevention promotes wellness maintenance (Neuman & Fawcett, 2002). With the success of tertiary intervention, the patient's wellness and conservation of energy leads back to primary prevention (Neuman & Fawcett, 2002).

The doctoral project showed how the anesthesia provider can integrate the Neuman model in their practice when treating CS patients. The patient maintains her health throughout her pregnancy with primary prevention. Primary prevention can be accomplished by regular doctor's visits, prenatal vitamins, proper diet and exercise, and adequate rest. If the obstetric physician determines that a CS will be the best method for delivery, it is the anesthesia provider's goal to ensure a safe and effective means of pain control, since surgery will be a stressor. The anesthesia provider can provide the secondary prevention by infusing IV acetaminophen preoperatively and providing an effective subarachnoid block containing intrathecal morphine. This intervention can reduce the amounts of opioids postoperatively which leads to the tertiary prevention. The tertiary intervention occurs when the patient is returning to her normal, stable state.

Essentials of Doctoral Education for Advanced Nursing Practice

The American Association of Colleges of Nursing (AACN) notes the practice-focused doctoral programs must require “a scholarly approach to the discipline, and a commitment to the advancement of the practice” (AACN, 2006, p. 3). The AACN urges nurses who are expanding their knowledge for advanced care become experts for scientific investigation and develop strong leadership skills. Ensuring the advanced nurse is competent for specialized practice, the AACN require these essentials to be incorporated in the education of the DNP degree.

Essential I

Essential I described the scientific underpinnings for practice and it is the foundation of nursing practices (Chism, 2013). This essential integrates nursing theories to guide practice which ensures optimal wellness of patients. Neuman’s model is the framework for this doctoral project. This project’s aim was to show that the use of IV acetaminophen used in a multimodal approach to pain therapy can help reduce the need of opioids in CS patients.

Essential II

DNP essential II explored the advancement of quality and safe healthcare delivery methods through scientific findings in nursing (Chism, 2013). The rates of cesarean delivery in the United States continue to rise. This project’s purpose was to show the addition of IV acetaminophen used in a multimodal approach for pain therapy may reduce postoperative pain and decrease the need for opioids for the CS patient.

Essential III

This essential focused on the integration of new research findings into nursing practice (Chism, 2013). In order to accomplish change, there is a need for quality improvement. By researching the literature and by a thorough collection of data, improvements to clinical outcomes can be implemented (Moran, Burson, & Conrad, 2014). Currently, no guidelines exist for pain control for the CS patient. This project's aim was to show that a multimodal approach to pain could be a safer and more effective means of reducing pain in the CS patient. Adding IV acetaminophen preoperatively and scheduled doses postoperatively should reduce the amounts of opioids needed postoperatively.

Essential IV

Chism (2013) illustrated that DNP graduates can improve patient care through information technology with this essential. Information for this project was compiled by using electronic databases. Peer-reviewed journals were located and suggested that improper pain management techniques for CS patients can lead to chronic pain and depression. This information indicated that a solution is necessary to improve pain management in this particular population. The utilization of electronic medical records was necessary to discover information for data analysis for this project.

Essential V

This essential accentuated the need for the DNP graduate to become involved with healthcare policy and advocacy (Chism, 2013). Once the advanced practice nurse becomes fluent with policies, this enables and prepares leadership positions for the DNP graduate. The results of this doctoral project may influence a change in practice by

promoting the need of a guideline to reduce pain for the CS patient. This guideline would incorporate the use of NOPAs, specifically IV acetaminophen to reduce the need of opioids.

Essential VI

This essential described the importance of collaboration between healthcare professionals (Chism, 2013). Professional collaboration can provide safe, effective, and timely patient care. This project showed the safety and efficacy of IV acetaminophen used in parturients who will deliver via cesarean section. The results of this project can help inform health care professionals of the benefits of a multimodal drug regimen to reduce opioid consumption.

Essential VII

Chism (2013) informed that essential seven illustrates that the advanced nurse is important for clinical prevention and improving the nation's health. Improper pain management in CS patients can lead to chronic pain, depression, and interfere with mother and infant bonding. This doctoral project entailed statistical analysis of pain outcomes by comparing those who received IV acetaminophen and those who did not. Statistical evaluation can show that the addition of IV acetaminophen can possibly improve pain scores and reduce the need of opioids in this patient population.

Essential VIII

The last essential ascertained that even though nursing is diverse, it is required for the DNP graduate to be an expert in at least one area of nursing practices (Chism, 2013). In order to complete this project, information was gathered and reviewed. Furthermore, the literature recommendations were put into practice to evaluate the effectiveness of IV

acetaminophen used in a multimodal regimen for CS patients. Inferred statistical analysis can be presented and reported for educational advancement.

Summary of Neuman Systems Model and DNP Essentials

Theories are tools that can be used to maximize the anesthesia provider's methods to assist patients to return to their normal state of functioning. The Neuman systems model is a wellness model that defined three interventions to enable a patient to return their prior functioning level. If lines of resistance and lines of defense fail from the result of external or internal stressors, primary, secondary, or tertiary interventions work independently or in tandem to achieve maximum wellness for the patient. The anesthesia provider can aid the cesarean section patient achieve maximum comfort postoperatively through a multimodal anesthesia technique. This multimodal technique combines neuraxial anesthesia with the addition of IV acetaminophen prior to surgical incision. IV acetaminophen can potentially help reduce the amounts of opioids needed postoperatively and encourage a faster and recovery of the patient.

DNP essentials can help ensure best care practices of the nurse anesthetist by encouraging the advanced nurse to become an expert in a certain area. The essentials encourage the advanced practice nurse to develop a complete course of action to care for the patient most sufficiently. Through advancing technology, integrating new research in nursing practice, collaborating with other healthcare providers, and becoming involved with healthcare policy and advocacy, the advanced nurse is more effective and can help improve overall patient satisfaction.

CHAPTER III - METHODOLOGY

Design

This project is a quantitative study that compared the relationship between mothers with CS who were given preoperative IV acetaminophen (Group A) and those mothers who did not (Group C) in order to determine the opioids used within 24 and 48-hour time period, length of hospital stay, and the amount time of first request of pain medication. The project incorporated the use of the independent *t*-test and Cohen's *d* test to measure the means and effect size of both groups. A cross sectional, retrospective chart review with quota sampling was used for the collection of data. A power analysis with alpha of 0.05 and an effect size of 0.4 indicated that 200 subjects were needed for each group (<https://www.ai-therapy.com/psychology-statistics/sample-size-calculator>).

Sample

The sampling frame consisted of women who presented for elective CS at a 211-bed hospital in southeast Mississippi between January 2014 through September 2016. Following IRB approval from USM and host facility charts were reviewed until 100 cases meeting inclusion criteria for each group were identified. Criteria selection consisted of cases regardless of parity, gravida, and presentation if they were:

- English speaking women
- American Society of Anesthesiologist Classification (ASA) I or II
- Ages between 18-35
- Gestation term of 37-42 weeks
- Singleton and multiple births
- Repeat CS

- Neuraxial block anesthesia
- Pfannestiel surgical incision

Exclusion criteria consisted of cases who had:

- Emergent or urgent CS
- Comorbidities that contributed to a higher ASA score
- Chronic pain
- Current infection
- Greater than four hours of labor time
- Liver and renal disease
- Sensitivities or allergic reactions to acetaminophen
- Patient-controlled analgesic pumps
- ICU admission after delivery
- General anesthesia or existing pain epidural
- Transverse surgical incision

Variables

Independent variables for the project included:

- ASA classification
- Single or twin delivery
- Race as identified by electronic health records (EHR) (Caucasian, African American, or Native American)
- Age in years
- Length of pregnancy in weeks

- Gravida defined as the number of pregnancies
- Parity defined as number of viable births
- Preoperative IV acetaminophen administration
- Postoperative acetaminophen administration
- Anesthesia start time
- Analgesics given postoperatively within 24 and 48 hours of anesthesia start time measured in morphine milligram equivalents measured by standard conversion chart (See Appendix E)

Dependent variables were:

- Analgesics including opioids or nonsteroidal anti-inflammatory drugs measured in morphine milligram equivalents (MME) given within a 24 and 48-hour time frame from anesthesia start time.
- LOS time measured in hours, beginning with anesthesia start time until patient was discharged home.
- Time of first request of pain medication was defined by the length of time between anesthesia start time and patient's first request for pain medication regardless of patient location and disposition.

Data Collection

The independent and dependent variables were collected from the electronic medication administration record (eMAR) and the EHR and was placed in the Data Collection Form (Appendix D). Data collected were entered into the Statistical Package for the Social Sciences (SPSS) (IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY: IBM Corp) for data analysis. The de-identified data was stored on a

password-protected personal computer. Data will be disposed by shredding or deleting from the hard drive six months after all graduation requirements and presentation/publication activities have been completed.

CHAPTER IV – ANALYSIS OF DATA

The aim of this project was to explore the relationship between IV acetaminophen and postoperative pain in CS patients. To determine the clinical impact of preoperative IV acetaminophen on postoperative pain in CS patients *t*-test were conducted to determine if statistical significance differences in postoperative pain medications, LOS, and time of first request of pain medication existed between women who received IV acetaminophen (Group A) and those who did not (Group C). Data met assumptions for *t*-test analysis. This chapter illustrates descriptive statistics and *t*-tests for four independent groups.

Descriptive Statistics

Descriptive statistics were used to describe cases in the sample including race, number of births, postoperative IV acetaminophen administration, gravida, parity, and pregnancy length. All cases consisted of women who were classified as ASA II classification. The following table describes the sample.

Table 1

Descriptive Statistics

Variable	N	Mean	Standard Deviation	Percentage (%)
Caucasian	114	-	-	57.00
African American	85	-	-	42.50
American Indian	1	-	-	0.50
Single Births	194	-	-	97.00
Twin Births	6	-	-	3.00
Postoperative IV Acetaminophen	90	-	-	45.00
Gravida	200	2.50	1.22	-
Parity	200	1.23	0.87	-
Length of Pregnancy	200	38.64	0.84	-

Bivariate Analysis

The Pearson's Chi-Square Test is an appropriate test for unpaired data, especially in large samples. This test was utilized to determine whether there were significant differences with regard to ASA, race, and birth at baseline among those who received or those who did not receive IV acetaminophen preoperatively (Table 2). The Pearson's Chi Square Test illustrated that there was no significant statistical difference at baseline for race ($p = 0.565$). Measures of association could not be computed for ASA and birth because there was no variability in the data. No significant differences between the two groups were identified.

Table 2

Baseline Categorical Variables Using Pearson's Chi-Square ($n = 200$)

Categorical Variable	Group A (n)	(%)	Group C (n)	(%)	p value
ASA	100	100.00	100	100.00	NA
Race	56	56.00	58	58.00	0.565
Births (single v. twins)	97	97.00	97	97.00	NA

Table 3

Baseline Continuous Variables Using An Independent t-test ($n = 200$)

Continuous Variable	Group A Mean	(sd)	Group C Mean	(sd)	p value
Gravida	2.43	1.257	2.57	1.17	.417
Parity	1.21	.092	1.24	0.82	.808
Weeks of Gestation	38.63	0.91	38.66	0.78	.802

Assumptions for Independent *t*-test

A series of two-tailed independent *t*-tests were used to determine if the administration of IV acetaminophen preoperatively decreased the total MME within 24 and 48 hours, the total LOS, and the time of first request of pain medication. Data met assumptions of normality and homogeneity of variance. See figures below.

Group MME 24 Hour MME	n	Mean	Std Dev	SEM	t	df	sig (2 tailed)	Mean Diff	SE Diff	95% Lower Bound	95% Upper Bound	Cohen's d
C	100	45.06	25.93	2.59								
A	100	47.01	23.95	2.40								
Pooled	200	46.04	24.95		-0.55	198	0.581	-1.95	3.53	-8.92	5.01	0.078

*Figure 2. MME for 24 Hours Independent *t*-test*

Equal Variances Assumed

There was no statistically significant difference in the scores for MME in the first 24-hour for Group A (M = 47.01, SD = 25.95) and Group C (M = 45.06, SD = 25.93); $t(198) = -0.55$, $p = 0.581$. Cohen's $d = 0.078$. These results indicate preoperative administration had no effect on postoperative use of analgesics at 24 hours. Cohen's d indicates there is a small effect size therefore, there is no statistical or practical differences between the two groups.

Group MME 48 Hour MME	n	Mean	Std Dev	SEM	t	df	sig (2 tailed)	Mean Diff	SE Diff	95% Lower Bound	95% Upper Bound	Cohen's d
C	100	47.95	24.98	2.50								
A	100	58.69	24.10	2.41								
Pooled	200	53.32	24.54		-3.10	198	0.002	-10.74	3.47	-17.588	-3.9	0.438

*Figure 3. MME for 48 Hours Independent *t*-test*

Equal Variances Assumed

There was a statistical significant difference in the scores for MME in the 48-hour for Group C (M = 47.95, SD = 24.98) when compared to Group A (M = 58.69, SD =

24.10); $t(198) = -3.10$, $p = 0.002$. Cohen's $d = 0.438$. These results indicate preoperative administration had no effect on postoperative use of analgesics at 48 hours and fewer analgesics were needed for Group C. Cohen's d indicates there is a small effect size therefore, there is no statistical or practical differences between the two groups.

Group LOS	n	Mean	Std Dev	SEM	t	df	sig (2 tailed)	Mean Diff	SE Diff	95% Lower Bound	95% Upper Bound	Cohen's d
C	100	52:19:00	6:31	0:39								
A	100	50:24:00	5:12	0:31								
Pooled	200	51:22:00	5:22		2.31	198.00	0.022	1:55	0:50	0:17	3:34	0.339

Figure 4. LOS Independent t-test

Equal Variance Assumed

There was a statistically significant difference in the scores for LOS for Group A ($M = 50:24$, $SD = 5:12$) compared to Group C ($M = 52:19$, $SD = 6:31$); $t(198) = 2.31$, $p = 0.022$. Cohen's $d = 0.339$. These results indicate preoperative administration had an effect on LOS for CS women. Cohen's d indicates there is a small effect size therefore, there is no statistical or practical differences between the two groups.

Group Time of First Request	n	Mean	Std Dev	SEM	t	df	sig (2 tailed)	Mean Diff	SE Diff	95% Lower Bound	95% Upper Bound	Cohen's d
C	100	5:22:00	5:35	0:33								
A	100	4:31:00	5:45	0:34								
Pooled	200	1:00:00	0:40		1.04	198	0.299	1:55	0:48	-0:44	2:25	0.17

Figure 5. Time of First Request Independent t-test

Equal Variance Assumed

There was no statistically significant difference in the scores for time of first request of pain medication for Group A ($M = 4:31$, $SD = 5:45$) when compared to Group C ($M = 5:22$, $SD = 5:35$); $t(198) = 1.04$, $p = 0.299$. Cohen's $d = 0.17$. These results

indicate preoperative administration had no effect on time of first request for pain medication. Cohen's d indicates there is a small effect size therefore, there is no statistical or practical differences between the two groups.

Conclusion of Data Analysis

An independent t -test was conducted to compare total MME with 24 and 48 hours, LOS, and time of first request of pain medication for CS patients who received preoperative doses of IV acetaminophen compared with CS patients who did not receive IV acetaminophen preoperatively. Data analysis revealed that LOS was statistically significant ($p = 0.022$) in Group A. The need for MME within 24 hours and time of first request was not significantly different between the two groups. Group C had a statistically significant decrease in MME within 48 hours ($p = 0.002$).

CHAPTER V – Conclusion

Discussion of Results and Limitations

The purpose of the retrospective chart review was to determine if the preoperative administration of IV acetaminophen reduced the amounts of MME needed post cesarean delivery within 24 and 48 hours, time for first intervention of analgesics, and length of stay for patients who received preoperative IV acetaminophen compared to those who did not. No statistical significant difference was observed between the two groups for MME within 24 hours of CS delivery and the amount of time for first request of pain medication. There was statistically significant difference that less MME were needed 48 hours after CS for group C when compared to group A. A statistical significant difference was reflected for those in Group A when comparing LOS. Data was collected and noted the presence and absence of adverse reactions. Fewer incidences of adverse reactions were documented for Group A when compared to Group C. No statistical analysis was conducted.

Neuman's Logic Model was used as the framework for this doctoral project. Group A revealed a shorter LOS at the hospital. The reduction of hospital stays aids with tertiary prevention. Tertiary prevention is a means to revert back to a normal state of wellness. This provides an opportunity for optimal wellness and stability.

Limitations and Barriers

Many limitations may have affected the results of the analysis. Distinct responses to pain vary in each individual and can contribute to the inconsistent amounts of pain medication required by each patient after cesarean delivery. Lack of consistency was observed in the administration times of IV acetaminophen prior to CS. In addition, only

45 percent of patients continued to receive postoperative administrations of IV acetaminophen after surgery. Scheduled NSAIDs were administered postoperatively to various patients while others did not receive this medication unless it was requested. A 0.4 effect size is a limitation because it is too small to find practical and statistical significance. Sample size may not have allowed the test to be as robust for statistical findings. The use of four different *t*-tests could have increased error terms and impacted the analysis. In addition, there could be an inherent difference between the literature's population and the population used for this project.

Time restrictions were a consistent barrier during data collection. In order to begin chart review, credentialing had to be obtained from the host facility. In addition, one person at the medical facility had authorization to upload charts into a query for review. These charts could only be reviewed Monday through Friday during the hours of 0800 to 1700.

Recommendations

It was noted that multiple types of opioids were used for breakthrough pain during and after surgery. The literature revealed in other studies that only one type of medication was used for breakthrough pain. Differences in mechanism of action and pharmacokinetics in various opioids and analgesics could cause variability and an increased amount of MME. Scheduled dosing could have contributed to a higher amount of MME between groups. A more consistent means of providing rescue medication and consistent IV acetaminophen administration times could have resulted in more favorable results and could be recommended for future studies.

Implications for Future Practice

Future adverse drug reactions and expected sequelae of opioid administration can be reviewed. It was observed without statistical testing that Group A had less amounts of adverse reactions. This retrospective chart review could be the premise to test if IV acetaminophen reduces nausea and vomiting, pruritus, and constipation, as well as any other measurable adverse reactions.

DNP Essentials Summary of Application

Essential IV focused on technology improving patient care. Electronic data bases were needed to search for peer-reviewed journals in order to investigate whether there is a need to treat pain postoperatively for CS mothers. EHR and eMAR were used to collect data for sampling. Essential VI expressed the importance of collaboration between healthcare professionals. It is crucial for the surgeon, anesthesia providers, and nurses all be consistent in treating postoperative pain for the CS mothers. Finally, Essential VII illustrated that the advanced practice nurse is important for improving the nation's help. Staying current on evidence-based practice encourages the best medical outcomes. Using a multimodal approach for CS patients can reduce the length of stay and potentially decrease unwanted adverse reactions and complications.


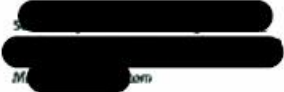
Conclusion

Literature revealed that IV acetaminophen can be used to reduce the amounts of opioids in major orthopedic surgical procedures, spine surgery, and various other procedures. However, this study did not illustrate a statistical significant reduction in the MME 24 or 48 hours after surgery or an increased time of first request of pain medication. The study did reveal a statistical significant reduction in the LOS. This


retrospective chart review gives a baseline of comparison for probable future studies, specifically for adverse complications or effects.

Since there is little literature concerning the use of IV acetaminophen used to reduce opioid use for CS patients, more studies may be needed. To assure that the results are valid or to determine if extraneous variables interfered with the results, a replication study may be indicated. Different populations, more sample groups, and a controlled study may offer reliable and valid results.




APPENDIX A – Merit Health Wesley IRB Approval

DATE: April 13, 2016

TO: Dana Bernardo, RN
FROM: Roger A. Flowers, M.Div. BCC *RA7*
 Wesley IRB Coordinator

This is to inform you that Merit Health Wesley IRB met on April 13, 2016 approving your proposed revision of the study: "Reduction of post cesarean section narcotic use with concomitant use of intravenous acetaminophen." The revision was approved to begin on April 13, 2016 and end on October 15, 2016. Dana Bernardo has been added as a principal investigator.


Please contact Cindy  In Health Information for the process of the chart review. Her number is . As soon as the study is complete, please contact Roger A. Flowers at  to close the study.

The IRB recommends the following items addressed would benefit the study, but is not necessary for IRB approval:

1. Was non-Opioid or non-opioid pain meds given? (Example: Toradol)
2. Were Intrathecal pain meds (narcotics) given during the C-section? (Example: Duramorph)
3. Was post-operative IV vs. oral narcotic use administered? (Example: Demerol IV vs. oral Percocet or Norco)
4. PCA vs. no PCA with C-section

Concerning pain measurements:

1. Was patient satisfied with pain management?
2. Was a Pain Scale Score used?

Cc: Cindy 
Dr. Michong Rayborn

Loving God, Serving Others, Excelling in Healthcare

APPENDIX B – IRB Approval Letter



INSTITUTIONAL REVIEW BOARD
118 College Drive #5147 | Hattiesburg, MS 39406-0001
Phone: 601.266.5997 | Fax: 601.266.4377 | www.usm.edu/research/institutional.review.board

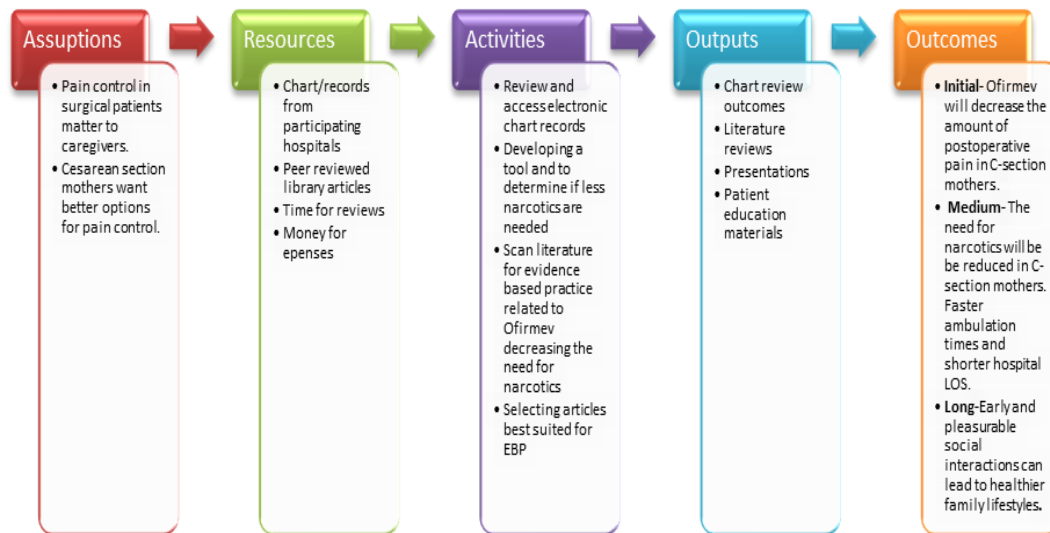
NOTICE OF COMMITTEE ACTION

The project has been reviewed by The University of Southern Mississippi Institutional Review Board in accordance with Federal Drug Administration regulations (21 CFR 26, 111), Department of Health and Human Services (45 CFR Part 46), and university guidelines to ensure adherence to the following criteria:

- The risks to subjects are minimized.
- The risks to subjects are reasonable in relation to the anticipated benefits.
- The selection of subjects is equitable.
- Informed consent is adequate and appropriately documented.
- Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of the subjects.
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of all data.
- Appropriate additional safeguards have been included to protect vulnerable subjects.
- Any unanticipated, serious, or continuing problems encountered regarding risks to subjects must be reported immediately, but not later than 10 days following the event. This should be reported to the IRB Office via the "Adverse Effect Report Form".
- If approved, the maximum period of approval is limited to twelve months.
Projects that exceed this period must submit an application for renewal or continuation.

PROTOCOL NUMBER: 16071302
PROJECT TITLE: Opioid use in the Cesarean Section Patient with the Preoperative Administration of Intravenous Acetaminophen
PROJECT TYPE: New Project
RESEARCHER(S): Dana Edwards Bernardo
COLLEGE/DIVISION: College of Nursing
DEPARTMENT: Nursing
FUNDING AGENCY/SPONSOR: N/A
IRB COMMITTEE ACTION: Exempt Review Approval
PERIOD OF APPROVAL: 07/19/2016 to 07/18/2017
Lawrence A. Hosman, Ph.D.
Institutional Review Board

APPENDIX C – Logic Model



APPENDIX D – Data Collection Sheet

CS Data Collection Form

AGE: _____ ASA: _____ Gestation (wks.): _____

Parity: _____ Birth: Single or Multiple

Race: _____ Co-morbidities: _____

Duration of Labor (hrs.): _____ Spinal: _____

Anesthesia Start Time: _____ Anesthesia Stop Time: _____

Procedure Start Time: _____ Procedure Stop Time: _____

Additional Procedures Indicated: _____

Receive IV acetaminophen: Y/N Time of IV Acetaminophen: _____

IV Acetaminophen post op: _____

Pain Medication							
Date/Time							
VAS/VPS							
Total Morphine Equivalents							
Totals							

PCA ordered: _____

Time from IV Acetaminophen to First Request Pain Medication:

Adverse Reactions: Y/N If Yes, Explain: _____

LOS in Hours (Admission to Discharge): _____

APPENDIX E – Morphine Milligram Equivalent (MME) Chart

Opioid or Analgesic	Morphine Milligram Equivalents (MME)
Oxycodone/acetaminophen	7.5
Hydrocodone/acetaminophen	5
Ketorolac	12
Ibuprofen	3.6
Naproxen	4
Roxicodone	7.5
Fentanyl	5
Meperidine	5
Hydromorphone	5
Acetaminophen/Codeine #3	4.5

Calculated by the author using industry stated formulas.

APPENDIX F – Literature Matrix

Author(s)	Year	Design	Frame work	Sample	Findings	Notes
1. Groudine & Fossum	2011	Qualitative study	None	9 different surgical procedures including major orthopedic surgery, abdominal gynecologic surgery, laparoscopic cholecystectomy, cesarean section, pediatric tonsillectomy, and laminectomy and discectomy procedures. Each procedure measured the efficacy of IV acetaminophen by comparing it with a placebo, with addition of steroids, comparing the synergism of the addition of a NSAID, or comparing it with IM meperidine.	This study showed the safety of this non-opioid analgesic. It also showed a reduction of postoperative pain and the amounts of opioids needed. It shows IV acetaminophen can be used in a multitude of operative procedures including pregnant and pediatric patients. This study assessed the efficacy of intravenous acetaminophen and compared many peer-reviewed studies.	This study shows many types of studies with different outcomes and variables. While this can be seen as a positive for IV acetaminophen, it can affect its significance. Due to the different studies and ways of testing its effectiveness, it is not consistent. In addition, many oral opioids contain acetaminophen. Therefore, it is important to monitor its administration by clinicians to prevent potential overdose.

2. Wininger, Miller, Minkowitz, Royal, Ang, Breitmeyer, & Singla	2010	Quantitative Study	None	In the U.S., 17 sites enrolled 244 adult subjects (ages 18-80) and arranged the subjects in 4 groups: IV acetaminophen 1000 mg [100 mL] q6h; IV acetaminophen 650 mg [65 mL] q4h; IV placebo 100 mL q6h; or IV placebo 65 mL q4h, each given as a 15-minute infusion after surgery for 24 hours.	It was determined that both administrations of IV acetaminophen (1000mg q6h and 650mg q4h) were associated with statistically significant analgesic efficacy compared to the placebo groups. It was noted that administrations of IV acetaminophen were well tolerated in both groups.	The results from this study are consistent with other studies comparing IV acetaminophen's effectiveness and safety with that of a placebo. It was looking at moderate to severe pain. This study was conducted at several clinical sites. No related hepatic SE were seen in the IV acetaminophen groups.
3. Pasero & Stannard	2012	Qualitative Case-Illustrated Study	None	This study reviews eight separate cases, including laparoscopic surgery, major abdominal surgery, dental surgery, and orthopedic procedures.	Results show that IV acetaminophen used in conjunction with other NSAIDs and opioids in a variety of operations, is effective in reducing pain and has less sedation when compared to opioid monotherapy alone. It is a safer drug with very few interactions	This study shows results of many surgical procedures including laparoscopic procedures, abdominal procedures, orthopedic, dental, and pediatric surgeries.

					with other medications.	
4. Marcario & Royal	2012	Quantitative Study	None	Sixteen articles from 2005 through 2010 from 9 countries were collected and reviewed. These articles contained 1,464 patients. Twenty-two comparison studies were analyzed.	This randomized-controlled trial showed that in 7 of 8 comparator studies, IV acetaminophen had similar analgesic outcomes. When comparing IV acetaminophen to placebo, 12 to the 14 studies found IV acetaminophen patients had better analgesic outcomes. Further information showed that 10 of the 14 studies showed less opioid consumption and longer time to first rescue.	This is a methodological RCT comparing IV acetaminophen to an active comparator and with a placebo.

5. De Oliveira, Castro-Alves & McCarthy	2015	Quantitative Study	None	Eleven RCTs were used to evaluate 740 patients, 375 having received a single dose of IV acetaminophen and the remaining 365, controls, receiving a placebo.	From the 11 RCTs, nine studies evaluated the effect of systemic acetaminophen and noted its ability to help reduce postoperative opioid consumption when compared to the control. There was a reduction of opioids needed by patients when given IV acetaminophen compared to placebo, weighted mean difference (WMD) of -9.7; 95% CI (-13.0 to -6.4). Also, the study showed IV acetaminophen was useful in a reduction of early pain at rest (≤ 4 h, -1; (95%CI (-2.0 to -0.2)) and pain at movement immediately postoperatively (24 h, -1.9; (95%CI (-2.8 to -1.0)) when compared to the control.	Researchers found that a single dose of IV acetaminophen is a valuable medication to help diminish postoperative pain.
6. Konstantatos, Smith, & Angliss	2012	Quantitative Study	None	For this study, 145 patients were divided as follows: pre and postoperative placebo (n = 50), operative	It was determined from the 3 groups that time ready for discharge from the postoperative	This study focused on the addition of IV acetaminophen administration

				IV acetaminophen and postoperative PO acetaminophen (n = 49), and pre and postoperative PO acetaminophen (n = 48).	care unit did not vary among the three groups.	tion to determine if the medication helped reduce discharge times in ambulatory surgery centers.
7. Wininger, Miller, Minkowitz Royal, Ang, Breitmeyer, & Singla	2010	Quantitative Study	None	For this study, 244 abdominal laparoscopic surgery patients were placed into four groups randomly: (a) IV acetaminophen 1 gm in 100 mL every 6 hours, (b) IV acetaminophen 650 mg in 65 mL every 4 hours, (c) 100 mL of IV placebo every 6 hours, and (d) 100 mL IV placebo every 4 hours.	The results showed that both IV acetaminophen groups outperformed the two placebo groups in terms of pain relief, reducing the weighted sum of pain intensity over a 24-hour period (1000 mg, $P < 0.0007$; 650 mg, $P < 0.019$).	This study is conducted in 17 facilities in the US. Laparoscopic surgery patients were randomly placed into four groups to compare IV acetaminophen to placebo. These medications were time scheduled and were given 24 hours after surgery.
8. Moon, Lee, Lee, & Moon	2011	Quantitative Study	None	For this study, 76 women who elected to have abdominal hysterectomies were divided into two groups. Group C, the control group and Group A, those who received	The results showed less need for opioids in Group A compared to group C ($P = 0.013$)	This study was a randomized, double-blinded and placebo-controlled, and was designed to learn whether IV

				IV acetaminophen .		acetaminophen administered prior to surgery would decrease pain scores, lessen the need for opioids, and reduce side effects.
9. Smith & Hoefling	2014	Quantitative Study	None	This study showed the results of 68 patients who underwent spinal surgery with anterior and posterior approaches. Half received IV acetaminophen and the other half was the control group.	Results indicated that there was a decreased need for opioids (11.3 mg morphine equivalent [ME]) in the group that received IV acetaminophen compared to the control group (20.6 ME). Both groups were similar when it came to visual analog pain scores (VAS) pain scores, and needing post-surgery anti-emetics and laxatives	An IV acetaminophen group used significantly less opioids ($p = 0.015$) compared to the control group in a retrospective analysis for spinal surgery.

10. Singla, Hale, Davis, Bekker, Gimbel, Jahr, Royal, Ang, & Viscusi	2014	Quantitative Study	None	This was a double-blind study and it reviewed 130 participants with similar demographics to determine efficacy and safety of a single-dose IV acetaminophen for patients who underwent THAs.	IV acetaminophen when compared to placebo, shows a higher mean pain intensity difference (PID) with significant ($P<0.5$) differences in treatment arms.	Two double-blind, parallel-group, multicenter, randomized, placebo-controlled clinical trials were conducted on 130 participants with similar demographics to determine efficacy and safety of a single-dose IV acetaminophen for patients who underwent THAs.
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11. Kamath & Lasrado	2014	Quantitative Study	None	<p>This study was a randomized parallel-group controlled trial. It compared the postoperative use of 1 gm of IV acetaminophen or 2 gm IV butorphanol for postoperative analgesia for cesarean section and other gynecological procedures. Tramadol was used as a rescue medication for breakthrough pain.</p>	<p>Either IV acetaminophen or IV butorphanol was given postoperatively . Pain intensity was measured with the VAS scores between the two groups at multiple time intervals for a 24-hour time period. Results showed that the butorphanol group had better pain rating within the first two hours but IV acetaminophen resulted in lower pain scores after six hours after surgical procedure. Within the 24-hour time period, the VAS scores were dramatically lower in the IV acetaminophen group ($p = 0.02$) when compared to the butorphanol group.</p>	<p>IV acetaminophen was an effective and safe analgesic, and that it provided better pain control-with fewer side effects-for the members of Group A than butorphanol provided for Group B ($p = 0.02$).</p>
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12. Paech, McDonnell, Sinha, Baber, & Nathan	2014	Quantitative Study	None	<p>This was a randomized, double blind, double-dummy, parallel group placebo-controlled clinical trial for patients having cesarean section with neuraxial anesthesia along with patient controlled epidural with pethidine. Patients were divided into three groups; control group who had placebo (Group C), those who received 40 mg of IV parecoxib and 400 mg of PO celecoxib at 12 hours (Group PC), 2 gm IV acetaminophen followed by 1 gm of the oral administration (Group PA), and the last two groups combined (Group PCPA).</p>	<p>The authors wanted to know if there was a decrease in the use of the patient controlled pethidine epidural infusion and postoperative pain for 111 women: Group C (n = 23), Group PC (n = 30), Group PA (n = 32), and Group PCPA (n = 26). A difference was not shown between the four groups regarding pethidine consumption ($p = 0.84$). Pain scores did not differ between the groups but the authors show that the request for tramadol was less in Group PCPA (incidence of 23% ($p = 0.004$) compared to 48%, 70%, and 58% for Group C, Group PC, and Group PA).</p>	<p>The dynamic pain scores, as measured by the verbal numerical rating score, were not different in the groups, but the need for PO tramadol was least needed in the PCPA group (incidence 23% versus 48%, 70% and 58% in groups C, PC, and PA respectively, $P = 0.004$).</p>
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13. Darvish, Ardestani, Shali, & Tajik	2013	Quantitative Study	None	<p>For this study, 120 subjects who had elective cesarean sections were randomly selected to show whether postoperative pain was controlled more effectively for those who received a diclofenac suppository postoperatively along with 1 gm of IV acetaminophen (Group A) or those who received a bolus of IV meperidine 20 mg (Group B) postoperatively. Meperidine was used for breakthrough pain and these results were compared.</p>	<p>Postoperative pain was less in Group A (23.3%) compared to Group B (38.3%), ($p = 0.009$). Six hours after surgery Group A experienced less pain than Group B, 16.7% and 38.7% respectively ($p = 0.010$). Pain was shown to be less 12 after surgery for Group A, $p = 0.002$. Meperidine used for breakthrough pain was the same for both groups postoperatively ($p > 0.5$). The addition of meperidine was less six hours postoperatively for Group A (6.7%) compared to Group B (26.7%), $p = 0.013$. After 12 hours, Group A need no additional Meperidine compared to Group B, which received 16.7% ($p = 0.004$).</p>	<p>The multimodal combination of diclofenac and IV acetaminophen was a better postoperative pain control method when compared to meperidine alone.</p>
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